

The Examiner is respectfully requested to enter the following response to the Second Restriction Requirement and Species election. The instant Requirement is both untimely and improper, having been issued after not only an earlier Restriction and/or Species Election Requirement (dated November 29, 2001), Applicants' response thereto (submitted January 28, 2002), a First Official Action on the merits of claims elected therein (dated April 10, 2002), and Applicants' detailed response to the First Action (submitted on August 12, 2002). All claims are believed to be in condition for allowance. Applicants therefore, respectfully request that the Office mail a Notice of Allowance, or at the very least, a communication that is responsive to Applicants' reply to the First Action on the merits.

RESPONSE

1. STATUS OF THE CLAIMS

Prior to the present Action, claims 1-17, 20-50, and 59-82 were pending in the case. No claims have been amended, added, or cancelled herein. Claims 1-17, 20-50, and 59-82 therefore remain pending in the case. For the convenience of the Examiner, a copy of the pending claims is attached as Exhibit A.

2. SECOND RESTRICTION/SPECIES ELECTION REQUIREMENT

Despite an earlier Restriction and/or Species Election Requirement, Applicants' response thereto, a First Official Action on the merits of all claims and Applicants' detailed response to the first Action, the instant Second Election Requirement has now been issued. The Second

Requirement apparently requires elections of species from the following allegedly patentably distinct species:

- a) a specific compound of the Formula (a);
- b) a specific component of the composition: gibberellin or cytokinin or lecithin;
- c) a specifically named vehicle; and
- d) any additional components that are required.

3. THE SECOND ELECTION IS UNTIMELY

Applicants respectfully point out that the Office is not following proper procedure, and this failure results in a delay of timely allowance of the patent to grant, potential loss of patent term, and undue economic burden on the Applicants for the consideration and response to the instant communication.

The present Election requirement is untimely. The Office has already issued one Restriction Requirement, to which Applicants have previously responded. Likewise, the Office has already issued a first Official Action on the merits that has already examined the generic claims and claims drawn to all species. After Applicants' response to the first Official Action, the examiner is required to reply to that response, address all arguments that have not already been responded to and provide an explanation should Applicant's arguments be deemed non-persuasive. M. P. E. P. §707.07. The issuance of this Second Election Requirement is a significant violation of standard Office procedure and is inconsistent with the provisions of 37 C. F. R. § 1.104, which states that "examination shall be complete with respect both to

compliance of the application with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form”.

Applicants note for the record that the Second Election Requirement is moot as claims drawn to all species *have already been examined*. Second, many of the so-called "species" set forth in the latest Action are, at best, sub-species. Third, the so-called species set forth in b) omit the claimed Tissue Factor or Tissue Factor derivatives.

4. THE SECOND ELECTION IS IMPROPER

The present Second Election Requirement is improper. 37 C. F. R. § 1.146 states that the Examiner may require the Applicant in the reply to *the first action* on an application containing a generic claim to a generic invention. (emphasis added). Since the Office has already issued one Restriction Requirement, to which Applicants have previously responded, this Second Election is Improper.

5. REQUEST FOR RECONSIDERATION OF REQUIREMENT

Pursuant to 37 C. F. R. § 1.143, Applicants traverse the election requirement and hereby request withdrawal of the present requirement for the reasons stated above.

6. PROVISIONAL ELECTION OF SPECIES IN VIEW OF REQUEST FOR RECONSIDERATION

Despite the earlier restriction, first Official Action on the merits that examined all species and Applicants' response, the Second Election Requirement now apparently requires an election of species. Applicants respectfully question whether the Office is truly seeking “the shortest

path to the final disposition of the application” as required by M. P. E. P. §707. In any event, pursuant to 37 C.F.R. § 1.111 and 37 C.F.R. § 1.146, Applicants nevertheless elect the following species:

(a) compound: *N*-lauroylethanolamine (NAE12:0)

Claims reading on species: 1-6, 9-17, 20-50, and 59-82

(b) component: lecithin

Claims reading on species: 1-17, 20-50, and 59-82

(c) vehicle: water

Claims reading on species: 1-17, 20-50, and 59-82

7. REQUEST FOR EXAMINER INTERVIEW

Pursuant to M. P. E. P. § 713.01 and 37 C.F.R. §1.133, Applicants hereby request the scheduling of an Interview with Examiner Pryor and Applicants' undersigned representative, Dr. Mark D. Moore, to discuss the pending claims as are now in condition for allowance, and to address any particular remaining issues in the mind of the Examiner, once he has had the opportunity to review this response and accompanying amendment. A telephone call to the Applicants' undersigned representative is earnestly solicited to arrange such interview within 30 days' receipt of this Amendment and Response by the Examiner.

8 SUMMARY

In conclusion, in light of the foregoing remarks, Applicants believe that the concerns set forth in the Action have now been overcome and that all pending claims are in condition for immediate allowance. Such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned at (713) 934-4084 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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